

## REMARKS

In the above-referenced Office Action the Examiner objected to the specification for a number of reasons. In support of this objection the Examiner stated, "This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

### Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.

1. Field of the Invention.

Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) Brief Summary of the Invention.

(g) Brief Description of the Several Views of the Drawing(s).

(h) Detailed Description of the Invention.

(I) Claim or Claims (commencing on a separate sheet).

(j) Abstract of the Disclosure (commencing on a separate sheet).

(k) Drawings.

(l) Sequence Listing (see 37 CFR 1.821-1.825)."

This objection has been rendered moot by the amendments made to the specification and the provision of an Abstract. Accordingly, the Examiner is respectfully requested to withdraw his objection to the specification.

The Examiner objected to Claims 7-9 under 37 CFR 1.75@ as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n).

The new claims 10-19 have no multiple dependencies and therefore this objection should be withdrawn by the Examiner.

Now turning to the more substantive issues the Examiner rejected, as best understood by him, Claims 1-3, 8 and 9, under 35 U.S.C. 102(b) as being anticipated by Carpentier, 5,814,100.

The Examiner further stated, "It should be noted that the intended use of the device as a voice prothesis is not give patentable weight. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art."

It is well settled patent law that in order for a reference to anticipate an invention each and every element of the claim must be present in the reference.

As amended claim 10 includes "a first retention flange disposed at said tracheal end of the body; a second retention flange at said esophageal end of the body... and a valve seat formed by said body at the esophageal end thereof;". Clearly the Carpentier reference does not teach or suggest that the valve body includes a valve seat formed thereon. Accordingly, the Examiner's rejection has been rendered moot by amended claim 10.

The Examiner next rejected Claims 1-9 under 35 U.S.C. 102(b) as being anticipated by Smith, 4,979,955. The Examiner also stated, "It should be noted that the intended use of the device as a voice prothesis is not give patentable weight. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention

and the prior art in order to patentably distinguish the claimed invention from the prior art."

This prior art reference likewise does not teach or suggest the above noted limitations now incorporated into amended claims 10-19 and the Examiner is requested to reconsider this reference based on these limitations.

Finally the Examiner rejected Claims 1-9 under 35 U.S.C. 102(b) as being anticipated by Pawlak, 5,135,538."

Once again the Examiner stated, "It should be noted that the intended use of the device as a voice prosthesis is not give patentable weight. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art."

Once again, the Smith reference does not teach or suggest the above noted limitations of amended claim 10 and the Examiner is requested to reconsider this reference based on these limitations.

It is respectfully that in claim 10 includes structural differences specific for the voice prosthesis between the invention as claimed and the prior art, viz. "a spoolshaped element", "valve closure normally seating against said valve seat"; "means providing a magnet force acting between the sealing surfaces"; said means comprising a magnet on one of the

valve closure or the valve seat, and a magnet or magnetically attractable material on the other of the valve closure and the valve seat".

In the event the Examiner has further difficulties with the allowance of the application, he is invited to contact the undersigned attorney by telephone at (412)380-0725 to resolve any remaining questions or issues by interview and/or by Examiner's amendment as to any matter that will expedite the completion of the prosecution of the application.

Respectfully submitted,

By: \_\_\_\_\_  
James O. Ray, Jr.  
Agent for Applicant  
Registration No. 27,666

JAMES RAY & ASSOCIATES  
2640 PITCAIRN ROAD  
MONROEVILLE, PA 15146

TELEPHONE: 412-380-0725  
FACSIMILE: 412-380-0748